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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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05/04/77 11/03/74 BARTLEY

1842, 0214

AMGEN INC
US PATENT OPERATIONS
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THOUSAND OAKS, CA 91320-1700

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

2/14/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 11/29/96 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 78-89 are pending in the application.

Of the above, claims are withdrawn from consideration.

2. ☒ Claims 1-77 have been cancelled.

3. ☐ Claims are allowed.

4. ☒ Claims 78-89 are rejected.

5. ☐ Claims are objected to.

6. ☐ Claims are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

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EXAMINER'S ACTION

Part III: Detailed Office Action

Newly submitted claims 78-89 are pending and under consideration.

Formal Matters:

5 The rejection of claims 75-77 under 35 U.S.C. § 112, first paragraph is withdrawn in view of applicants' arguments and/or amendments.

10 Applicants have submitted an extensive, 14 page PTO-1449 with their response. In the previous Office Action, applicants were invited to submit copies of reference which had properly been cited, but of which copies were unavailable. Of the references on the instant PTO-1449, only citations B1, B4, B6, B8-B10, B13, B21, C13, C23, C27, C28, C30, C32, C34-C37, C42,
X C44, C45, C48, C49, C53, C55, C58, C72, C76, C84, C85, C87, C101, C114, C117, C120, C131, C136, C143, C146, C151, C152, C153, C156-C160, C165, C177, C185, C196, C236 and C237 meet this criterion. Of those, copies of reference C32 (Francis et al.) and C177 (Fisher et al.)
15 were not submitted, therefore these references have not been considered. The remainder of the listed references have either already been made of record, or alternatively are not in compliance with the provisions of MPEP 609, and have therefore not been considered.

20 The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

 The oath or declaration is defective because:

25 It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. § 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Applicants intention to file a substitute declaration is noted; however, no such paper

accompanied the amendment filed 11/29/96.

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 11/29/96 have been approved.

5

The amendment filed 11/29/96 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: in adding the appropriate cross reference to related applications
10 to the specification as required by the Examiner, applicants additionally included a phrase
✓ incorporating by reference those related applications. Insofar as any material may exist in those
related applications which did not appear in the instant specification as filed, such incorporation
by reference after the filing date of the instant application constitutes new matter. Applicants are
reminded that a claim to priority to an earlier filed application is not synonymous with
15 incorporation by reference of all material disclosed therein.

Applicant is required to cancel the new matter in the response to this Office action.

The specification remains objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(I). Correction of the
20 following is required: There is no basis in the specification for the limitation of a nucleic acid
✓ encoding a polypeptide having as its C-terminus an amino acid from positions 172-265 of Figure
11. Although such would be enabled by the specification, there is no indication in the
specification that this particular range was envisioned.

Applicants traversal of this objection is noted, but is not deemed persuasive. Applicants
25 have erroneously interpreted this objection as a rejection under 35 U.S.C. §112, first paragraph,
which it is not. This is merely an objection that the specification does not support the limitation.
As the limitation was found in originally filed claims, applicants may properly correct the
problem by amending the specification to recite the particular limitation, so long as it is recited

in a manner equivalent to as disclosed in the original claims, without having such an amendment considered to be new matter.

Double Patenting Rejections:

5 The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761
10 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground
15 provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR
20 3.73(b).

Claims 78-89 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-44 of copending application Serial No. 08/252628. Although the conflicting claims are not identical, they are not patentably distinct
25 from each other because the instant claims are drawn to fragments of the nucleic acids of the copending claims, which fragments are not patentably distinct from the nucleic acid encoding the protein in its entirety.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants arguments filed 11/29/96 have been fully considered but are not deemed persuasive. Applicants argument of *Genentech v. Wellcome* is noted. However, the issues involved in an infringement trial are not the same as those involved in determining patentable distinctness of two inventions. In the instant case, the Examiner maintains the position that the truncated DNAs are obvious over the full length, as it would have been obvious to the person of ordinary skill in the art, having the full length, to use subsets of such for example as hybridization probes, etc. Thus, the claimed compositions themselves are obvious. With regard to applicants argument that it would not have been predictable that such truncations would retain the ability to encode a protein with biological activity, it is noted that such a property is merely an inherent property of the obvious nucleic acids. It has long been established that mere recitation of a newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art (*In re Swinehart and Sfligoj*, 169 USPQ 226).

Revised
on request
for
consideration

Applicants further arguments that the Patent Office has issued numerous patents to truncated *proteins* based on previously known *proteins* is not persuasive, as the issue here is the obviousness of the nucleic acids which encode the proteins, which are considered obvious for reasons cited immediately above. Further, each case must be examined on its individual merits; the fact that truncations of one molecule have been found to be allowable does not impart allowability to all possible similar claims in unrelated cases.

The Examiner notes that no provisional double patenting rejections over the claims of Application Serial No. 08/321488 are applicable.

Advisory Information:

Applicant's amendment necessitated the new grounds of objection/rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the

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Art Unit 1812

extension of time policy as set forth in 37 C.F.R. § 1.136(a).


5 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION
IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE
EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE
OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER
THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE
SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY
ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a)
10 WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN
NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX
MONTHS FROM THE DATE OF THIS FINAL ACTION.


15 Any inquiry concerning this communication or earlier communications from the Examiner
should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr.
Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

20 If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's
supervisor, Dr. Stephen Walsh, can be reached at (703)308-2957.

Any inquiry of a general nature or relating to the status of this application should be
directed to the Group receptionist at telephone number (703) 308-0196.

25 Certain papers related to this application may be submitted to Group 1800 by facsimile
transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal
Mall 1 (CM1). The faxing of such papers must conform with the notices published in the
Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see
37 C.F.R. § 1.6(d)). The Art Unit 1812 Fax Center number is (703) 308-0294. NOTE: If
Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant
30 or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to
avoid the processing of duplicate papers in the Office. Please advise the Examiner at the
telephone number above when a fax is being transmitted.

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STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800